Logic Model: Study Design

**Audience:** Sponsors/CROs, sites/investigators

**Purpose:** To provide a sample of activities, linked to their intended effects (outputs, outcomes and impact), that might be considered during study design for a clinical trial aiming to enroll a representative population. A non-exhaustive sample of key performance indicators for such a study design is also provided in order to demonstrate how this logic model can be used to construct performance metrics.

**Considerations for use:**

- See *Introduction to Logic Models* for detailed instruction on the use of logic models in general and as related to the *Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document*.
- Most activities defined in this logic model are routine in a typical study design process. The logic model provides a framework for thinking about these activities through the lens of diverse enrollment.
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**INPUTS**

- Value for resources
- Staff time

**ACTIVITIES**

- Identify study question, epidemiology of disease and target population
- Solicit relevant patient and community input on study question and relevance
- Define demographic and non-demographic variables required to answer study question
- Define all feasible analytic methods to answer study question
- Plan for testing heterogeneity of treatment effect
- Create broadest possible eligibility criteria, justified ethically or scientifically

**OUTPUTS**

- Study question, epidemiology of disease and target population described in protocol
- Evidence of patient or community input during study design process
- Case report forms available with defined demographic and non-demographic variables
- Data analysis plan contains all feasible analytic methods to answer study question
- Analytic methods for testing heterogeneity of treatment effect detailed in data analysis plan
- Protocol contains scientific or ethical justification for each excluded population

**OUTCOMES**

**SHORT**

- Study question, data collection and analysis methods are informed by epidemiology of disease and relevant patient input
- Materials available to collect and analyze subgroup-specific data

**MED/LONG**

- Clinical trial population representative of patient population
- Target subgroup data collection/analysis materials available for future use
- Drug with efficacy and safety/risk evidence in representative populations

**IMPACT**

- Widespread understanding of heterogeneity of effect of marketed drug
- Decrease in health disparities for disease area (aspirational)